IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

1. UNITED STATES OF AMERICA,

Plaintiff,

v.

- 1. 250,000 filled bottles of liquid product, more or less, of finished product, containing kratom, labeled in part: "Botanic Tonics Feel Free Plant Based Herbal Supplement",
- 2. 1.5 tanks of liquid product, more or less, containing kratom,
- 3. 1,200 cartons of capsules, more or less, of kratom, labeled in part: "Botanic Tonics Feel Free Plant Based Herbal Supplement",
- 4. Undetermined quantities of bulk powder kratom, labeled in part: "Green Nano",

and

5. All other quantities of the aforesaid articles of food with any lot number and in any size or type container that are labeled or otherwise appear to contain, or are, kratom, located at 13105 East 61st Street, Suites A&B Broken Arrow, Oklahoma 74012-1191.

Defendant Articles.

FILED

APR 26 2023

Mark C. McCartt, Clerk U.S. DISTRICT COURT

23 CV - 16 8 JFH - CDL

Case No.

Verified Complaint for Forfeiture In Rem

NOW COMES the United States of America, by its attorneys, Clinton J.

Johnson, United States Attorney for the Northern District of Oklahoma, and Kristin

Harrington, Assistant United States Attorney, respectfully stating as follows:

NATURE OF THE ACTION

1. This is a civil forfeiture action *in rem* brought by the United States of America pursuant to 21 U.S.C. § 334 to seize and condemn the Defendant Articles identified in the caption, located on the premises of Botanic Tonics, LLC, ("Botanic Tonics"), 13105 East 61st Street, Suites A&B Broken Arrow, Oklahoma 74012-1191, because they violate the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 301 *et seq.*

JURISDICTION AND VENUE

- 2. This Court has jurisdiction over seizures brought by the United States under 28 U.S.C. § 1345 and under 21 U.S.C. § 334.
- 3. The Defendant Articles are articles of food, within the meaning of 21 U.S.C. §§ 321(f) and 321(ff), located on the premises of Botanic Tonics, 13105 East 61st Street, Suites A&B Broken Arrow, Oklahoma 74012-1191.
- 4. This Court has *in rem* jurisdiction over the Defendant Articles, and venue is proper under 28 U.S.C. § 1395(b) and 21 U.S.C. § 334(a)(1), because the Defendant Articles are located in the Northern District of Oklahoma.
- 5. The Defendant Articles consist in whole or in part of components that were shipped in interstate commerce from outside the state of Oklahoma.

FACTS

6. Botanic Tonics manufactures, holds, and distributes dietary supplements, labeled as Botanic Tonics Feel Free Plant Based Herbal Supplement

that contain *Mitragyna speciosa*, also known as kratom, in liquid form and packaged in bottles, in capsule form and packaged in sealed pouches, and Botanic Tonics receives bulk powder kratom that is used in its production of dietary supplements.

- 7. As a plant, kratom is a botanical and, therefore, a dietary ingredient within the meaning of 21 U.S.C. § 321(ff)(1)(C). Because kratom was not marketed as a dietary ingredient in the United States prior to October 15, 1994, it is a new dietary ingredient within the meaning of 21 U.S.C. § 350b(d). The Defendant Articles are dietary supplements within the meaning of 21 U.S.C. § 321(ff), and they do not fall within an exception set forth in 21 U.S.C. § 321(ff)(3)(B).
- 8. Investigators from the United States Food and Drug Administration ("FDA") conducted an inspection of the premises of Botanic Tonics, 13105 East 61st Street, Suites A&B Broken Arrow, Oklahoma 74012-1191, between October 17, and November 17, 2022. During the inspection, FDA investigators observed large quantities of products similar to the Defendant Articles, including bottles of Feel Free Plant Based Herbal Supplement, labeled as containing kratom and as a dietary supplement; and large quantities of bulk kratom powder, used by Botanic Tonics to manufacture its dietary supplements.
- 9. On or around January 2023, FDA documented that Botanic Tonics' social media webpage (facebook.com/botanictonics) advertised packages of Feel Free Plant Based Herbal Supplement capsules. FDA then purchased Botanic Tonics' Feel Free Plant Based Herbal Supplement capsules on or around February 2023 from https://botanictonics.com. FDA received a shipment from Botanic Tonics, located

in Broken Arrow, Oklahoma, of Botanic Tonics' Feel Free Plant Based Herbal Supplement capsules on or around March 2023. Botanic Tonics' Feel Free Plant Based Herbal Supplement capsules were labeled as containing kratom and as a dietary supplement.

- 10. Investigators from FDA conducted an inspection of Botanic Tonics on April 26, 2023. During the inspection, FDA investigators observed large quantities of products similar to the Defendant Articles, including large quantities of Feel Free Plant Based Herbal Supplement liquid, labeled as containing kratom and as a dietary supplement; large quantities of Botanic Tonics' Feel Free Plant Based Herbal Supplement capsules labeled as containing kratom and as a dietary supplement; and large quantities of bulk kratom powder, used by Botanic Tonics to manufacture its dietary supplements.
- 11. Serious safety concerns exist regarding the effect of kratom on multiple organ systems. Consumption of kratom can lead to a number of negative health impacts, including respiratory depression, vomiting, nervousness, weight loss, and constipation. Kratom consumption has been linked to neurologic, analgesic and sedative effects, addiction, and liver toxicity.
- 12. Mitragynine, the major alkaloid identified in kratom, has been reported as a partial opioid agonist, producing effects that are similar to morphine.

 Furthermore, a minor alkaloid of kratom, 7-hydroxymitragynine, has been reported to be even more potent than morphine. *Mitragyna speciosa* preparations have significant effects on cognition in humans.

13. *Mitragyna speciosa* has been indicated to have both narcotic and stimulant-like effects, which substantiates its potential for abuse. Chronic exposure to *Mitragyna speciosa* preparations can be followed by withdrawal symptoms in humans, some typical withdrawal symptoms include hostility, aggression, excessive tearing, inability to work, arching of muscle, bones, and jerk limb movements.

BASIS FOR FORFEITURE

- 14. The allegations in the preceding paragraphs are re-alleged and incorporated by reference.
- 15. The Defendant Articles are dietary supplements and dietary ingredients within the meaning of the Act, 21 U.S.C. §§ 321(ff) and 321(ff)(1), that may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 331(a) because they are adulterated within the meaning of 21 U.S.C. § 342(f)(1)(B).
- 16. The Defendant Articles are adulterated within the meaning of 21 U.S.C. § 342(f)(1)(B) in that they contain or are a new dietary ingredient, kratom, for which there is inadequate information to provide reasonable assurance that this ingredient does not present a significant or unreasonable risk of illness of injury.
- 17. Based on the foregoing, the Defendant Articles are held illegally within the jurisdiction of this Court and are liable to seizure, forfeiture, and condemnation pursuant to 21 U.S.C. § 334.

CLAIM FOR RELIEF

WHEREFORE, the United States requests that a warrant to arrest the Defendant Articles be issued; that notice be given to all persons having any interest in the articles to appear herein and show cause why the seizure and condemnation should not be decreed; that judgment be entered declaring that the Defendant Articles be condemned and disposed of according to law, and that the United States be granted such other and further relief as this Court may deem just and proper, together with costs and disbursement of this action.

DATED: April 26, 2023.

RESPECTFULLY SUBMITTED,

CLINTON J. JOHNSON UNITED STATES ATTORNEY

Bv:

KRISTIN F. HARRINGTON, OBA No. 21185

Assistant United States Attorney 110 West 7th Street, Suite 300

Tulsa, Oklahoma 74119

T: (918) 382-2785 | F: (918) 560-7938 Email: Kristin.Harrington@usdoj.gov VERIFICATION

I, Chad J. Whitwell, Compliance Officer for the Food and Drug Administration,

U.S. Department of Health and Human Services, declare under penalty of perjury

that I have read the foregoing Verified Complaint for Forfeiture In Rem in this action

and state that the allegations it contains are true and correct to the best of my

knowledge, information, and belief.

The sources of my knowledge and information and the grounds of my belief are

the official files and records of the United States, as well as my investigation of this

case, together with others, as a Compliance Officer, Division 3 West, United States

Food and Drug Administration.

Executed on the 26th day of April, 2023, in Tulsa, Oklahoma.

Compliance/Consumer Safety Officer

Food and Drug Administration U.S. Department of Health and Human Services